

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Confirmation No.: 9273

Application No.: 10/754,547 Group Art Unit: 1614

Filing Date: January 12, 2004 Examiner:

For: METHODS OF TREATING AN Attorney Docket No.: 81481-300

INFLAMMATORY-RELATED DISEASE

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to Applicant's duty of disclosure under 37 C.F.R. § 1.56, enclosed is a Form PTO-1449 listing seventy-three (73) references, copies of which are provided for the Examiner's convenience.

It is respectfully requested that the references be made of record in this application by the Examiner's completion and return of the attached Form PTO-1449.

This Information Disclosure Statement is filed under § 37 C.F.R. 1.97(b)(3), prior to the mailing of a first Office Action on the merits. Thus, no fee is believed to be due. However, the Commissioner is authorized to charge any fees which may be required to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

Rodney J. Fuller

Or. Allali A. Fallucci

(Reg. No. 46,714)

(Reg. No. 30,256)

WINSTON & STRAWN LLP

Customer No. 28765

202-371-5904

11/02/04

LIST OF REFERENCES CITED BY APPLICANT Form PTO-1449 Was several sheets if necessary) Sheet 1 of 4 ATTY. DOCKET NO.: 81481-300 APPLICATION NO.: 10/754,547 APPLICANT: Longgui WANG et al. FILING DATE: January 12, 2004 1614

RADEMA	<u> </u>
RADEMI	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
CI	Andreakos, E. T. et al. Cytokines and anti-cytokine biologicals in autoimmunity: present and future. Cytokine Growth Factor Rev, 13: 299-313, 2002.
C2	Antoni, C. et al. Side effects of anti-TNF therapy: current knowledge. Clin Exp Rheumatol, 20: S152-157, 2002.
C3	Autschbach, F. et al. In situ expression of interleukin-10 in noninflamed human gut and in inflammatory bowel disease. Am J Pathol, 153: 121-130, 1998.
C4	Bebo, B. F., Jr. et al. Hypothesis: a possible role for mast cells and their inflammatory mediators in the pathogenesis of autoimmune encephalomyelitis. J Neurosci Res, 45: 340-348, 1996.
C5	Bessis, N. et al. Gene therapy for rheumatoid arthritis. J Gene Med, 4: 581-591, 2002.
C6	Bresnihan, B. et al. Treatment of rheumatoid arthritis with recombinant human interleukin-1 receptor antagonist. Arthritis Rheum, 41: 2196-2204, 1998.
C7	Brown, S. L. et al. Tumor necrosis factor antagonist therapy and lymphoma development: twenty-six cases reported to the Food and Drug Administration. Arthritis Rheum, 46: 3151-3158, 2002.
C8	Brynskov, J. et al. Increased concentrations of interleukin 1 beta, interleukin-2, and soluble interleukin-2 receptors in endoscopical mucosal biopsy specimens with active inflammatory bowel disease. Gut, 33: 55-58, 1992.
C9	Campion, G. V. et al. Dose-range and dose-frequency study of recombinant human interleukin-1 receptor antagonist in patients with rheumatoid arthritis. The IL-1Ra Arthritis Study Group. Arthritis Rheum, 39: 1092-1101, 1996.
C10	de Jong, B. A., Huizinga, T. W., Bollen, E. L., Uitdehaag, B. M., Bosma, G. P., van Buchem, M. A., Remarque, E. J., Burgmans, A. C., Kalkers, N. F., Polman, C. H., and Westendorp, R. G. Production of IL-1beta and IL-1Ra as risk factors for susceptibility and progression of relapse-onset multiple sclerosis. J Neuroimmunol, 126: 172-179, 2002.
C11	Dean, J. L., Wait, R., Mahtani, K. R., Sully, G., Clark, A. R., and Saklatvala, J. The 3' untranslated region of tumor necrosis factor alpha mRNA is a target of the mRNA-stabilizing factor HuR. Mol Cell Biol, 21: 721-730, 2001.
C12	
C13	Detmar, M., Brown, L. F., Claffey, K. P., Yeo, K. T., Kocher, O., Jackman, R. W., Berse, B., and Dvorak, H. F. Overexpression of vascular permeability factor/vascular endothelial growth factor and its receptors in psoriasis. J Exp Med, 180: 1141-1146, 1994.
C14	Dickson, D. W., Lee, S. C., Mattiace, L. A., Yen, S. H., and Brosnan, C. Microglia and cytokines in neurological disease, with special reference to AIDS and Alzheimer's disease. Glia, 7: 75-83, 1993.
C15	Dustin, M. L., Rothlein, R., Bhan, A. K., Dinarello, C. A., and Springer, T. A. Induction by IL 1 and interferon-gamma: tissue distribution, biochemistry, and function of a natural adherence molecule (ICAM-1). J Immunol, 137: 245-254, 1986.
C16	rheumatoid arthritis. Lancet, 344: 1125-1127, 1994.
C17	Blood Rev, 17: 233-240, 2003.
C18	Feldmann, M. Pathogenesis of arthritis: recent research progress. Nat Immunol, 2: 771-773, 2001.
C19	Glabinski, A. et al., Chemokine upregulation follows cytokine expression in chronic relapsing experimental autoimmune encephalomyelitis. Scand J Immunol, 58: 81-88, 2003.

EXAMINER	DATE CONSIDERED	
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conformance and not considered. Include copy of this form with next communication to applicant.		

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	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
C20	Grossman, R. M. et al., Interleukin 6 is expressed in high levels in psoriatic skin and stimulates proliferation of cultured human keratinocytes. Proc Natl Acad Sci U S A, 86: 6367-6371, 1989.
C21	Guha, M. et al., LPS induction of gene expression in human monocytes. Cell Signal, 13: 85-94, 2001.
C22	Guha, M., et al., Lipopolysaccharide activation of the MEK-ERK1/2 pathway in human monocytic cells mediates tissue factor and tumor necrosis factor alpha expression by inducing Elk-1 phosphorylation and Egr-1 expression. Blood, 98: 1429-1439, 2001.
C23	Haversen, L. et al., Lactoferrin down-regulates the LPS-induced cytokine production in monocytic cells via NF-kappa B. Cell Immunol, 220: 83-95, 2002.
C24	Hotamisligil, G. S. et al., Tumor necrosis factor alpha inhibits signaling from the insulin receptor. Proc Natl Acad Sci U S A, 91: 4854-4858, 1994.
C25	Hotamisligil, G. S. et al., Adipose expression of tumor necrosis factor-alpha: direct role in obesity-linked insulin resistance. Science, 259: 87-91, 1993.
C26	Indaram, A. V. et al., Elevated basal intestinal mucosal cytokine levels in asymptomatic first-degree relatives of patients with Crohn's disease. World J Gastroenterol, 6: 49-52, 2000.
C27	Indaram, A. V.et al., Mucosal cytokine production in radiation-induced proctosigmoiditis compared with inflammatory bowel disease. Am J Gastroenterol, 95: 1221-1225, 2000.
C28	Isaacs, K. L. et al., Cytokine messenger RNA profiles in inflammatory bowel disease mucosa detected by polymerase chain reaction amplification. Gastroenterology, 103: 1587-1595, 1992.
C29	Ishihara, K. et al., IL-6 in autoimmune disease and chronic inflammatory proliferative disease. Cytokine Growth Factor Rev, 13: 357-368, 2002.
C30	Jun, H. S. et al., Absolute requirement of macrophages for the development and activation of beta-cell cytotoxic CD8+ T-cells in T-cell receptor transgenic NOD mice. Diabetes, 48: 34-42, 1999.
C31	Kong, M. et al., Cyclin F regulates the nuclear localization of cyclin B1 through a cyclin-cyclin interaction. Embo J, 19: 1378-1388, 2000.
C32	Laliberte, R. E. et al., Glutathione s-transferase omega 1-1 is a target of cytokine release inhibitory drugs and may be responsible for their effect on interleukin-1beta posttranslational processing. J Biol Chem, 278: 16567-16578, 2003.
C33	Lang, C. H. et al., Tumor necrosis factor impairs insulin action on peripheral glucose disposal and hepatic glucose output. Endocrinology, 130: 43-52, 1992.
C34	Lechman, E. R. et al., Direct adenoviral gene transfer of viral IL-10 to rabbit knees with experimental arthritis ameliorates disease in both injected and contralateral control knees. J Immunol, 163: 2202-2208, 1999.
C35	Li, Y. J. et al., Glutathione S-Transferase Omega 1 modifies age-at-onset of Alzheimer Disease and Parkinson Disease. Hum Mol Genet, 12: 3259-3267, 2003.
C36	Lindsberg, P. J. et al., Inflammation and infections as risk factors for ischemic stroke. Stroke, 34: 2518-2532, 2003.
C37	Liu, J. H. et al., Functional association of TGF-beta receptor II with cyclin B. Oncogene, 18: 269-275, 1999.
C38	MacDermott, R. P. Alterations in the mucosal immune system in ulcerative colitis and Crohn's disease. Med Clin North Am, 78: 1207-1231, 1994.
C39	Matsuura, T. et al., Immune activation genes in inflammatory bowel disease. Gastroenterology, 104: 448-458, 1993.

EXAMINER	DATE CONSIDERED
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	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
C40	McGeer, E. G. et al., Inflammatory processes in Alzheimer's disease. Prog Neuropsychopharmacol Biol Psychiatry, 27: 741-749, 2003.
C41	McGovern, S. L. et al., Kinase inhibitors: not just for kinases anymore. J Med Chem, 46: 1478-1483, 2003.
C42	Mendonca, C. O. et al., Current concepts in psoriasis and its treatment. Pharmacol Ther, 99: 133-147, 2003.
C43	Mennicken, F. et al., Chemokines and chemokine receptors in the CNS: a possible role in neuroinflammation and patterning. Trends Pharmacol Sci, 20: 73-78, 1999.
C44	Moreland, L. W. et al., Treatment of rheumatoid arthritis with a recombinant human tumor necrosis factor receptor (p75)-Fc fusion protein. N Engl J Med, 337: 141-147, 1997.
C45	Najarian, D. J. et al., Connections between psoriasis and Crohn's disease. J Am Acad Dermatol, 48: 805-821; quiz 822-804, 2003.
C46	Noguchi, M. et al., Secretion imbalance between tumour necrosis factor and its inhibitor in inflammatory bowel disease. Gut, 43: 203-209, 1998.
C47	Ofei, F. et al., Effects of an engineered human anti-TNF-alpha antibody (CDP571) on insulin sensitivity and glycemic control in patients with NIDDM. Diabetes, 45: 881-885, 1996.
C48	Okayasu, I. et al., A novel method in the induction of reliable experimental acute and chronic ulcerative colitis in mice. Gastroenterology, 98: 694-702, 1990.
C49	Osman, F. et al., A cis-acting element in the 3'-untranslated region of human TNF-alpha mRNA renders splicing dependent on the activation of protein kinase PKR. Genes Dev, 13: 3280-3293, 1999.
C50	Rabinovitch, A. et al., Role of cytokines in the pathogenesis of autoimmune diabetes mellitus. Rev Endocr Metab Disord, 4: 291-299, 2003.
C51	Ruan, H., et al., Insulin resistance in adipose tissue: direct and indirect effects of tumor necrosis factor- alpha. Cytokine Growth Factor Rev, 14: 447-455, 2003.
C52	Ruan, H. et al., Troglitazone antagonizes tumor necrosis factor-alpha-induced reprogramming of adipocyte gene expression by inhibiting the transcriptional regulatory functions of NF-kappaB. J Biol Chem, 278: 28181-28192, 2003.
C53	Rutgeerts, P., A critical assessment of new therapies in inflammatory bowel disease. J Gastroenterol Hepatol, 17 Suppl: S176-185, 2002.
C54	Samoilova, E. B. et al., IL-6-deficient mice are resistant to experimental autoimmune encephalomyelitis: roles of IL-6 in the activation and differentiation of autoreactive T cells. J Immunol, 161: 6480-6486, 1998.
C55	Schon, M. P. Animal models of psoriasis - what can we learn from them? J Invest Dermatol, 112: 405-410, 1999.
C56	Schreiber, A. B. et al., Transforming growth factor-alpha: a more potent angiogenic mediator than epidermal growth factor. Science, 232: 1250-1253, 1986.
C57	Schreiber, S. et al., Immunoregulatory role of interleukin 10 in patients with inflammatory bowel disease. Gastroenterology, 108: 1434-1444, 1995.
C58	Schumann, R. R. et al., Lipopolysaccharide activates caspase-1 (interleukin-1-converting enzyme) in cultured monocytic and endothelial cells. Blood, 91: 577-584, 1998.
C59	Strange, P. et al., Interferon gamma-treated keratinocytes activate T cells in the presence of superantigens: involvement of major histocompatibility complex class II molecules. J Invest Dermatol, 102: 150-154, 1994.

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	OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)
C60	Subramanian, N. et al., Interleukin 1 releases histamine from human basophils and mast cells in vitro. J Immunol, 138: 271-275, 1987.
C61	Sullivan, G. W. et al., The role of inflammation in vascular diseases. J Leukoc Biol, 67: 591-602, 2000.
C62	Suri, A. et al., Dissecting the role of CD4+ T cells in autoimmune diabetes through the use of TCR transgenic mice. Immunol Rev, 169: 55-65, 1999.
C63	Tanaka, Y. et al., Inter- and intracellular signaling in secondary osteoporosis. J Bone Miner Metab, 21: 61-66, 2003.
C64	Tang, X. et al., Identification and functional characterization of a novel binding site on TNF-alpha promoter. Proc Natl Acad Sci U S A, 100: 4096-4101, 2003.
C65	Tsuchiya, S. et al., Establishment and characterization of a human acute monocytic leukemia cell line (THP-1). Int J Cancer, 26: 171-176, 1980.
C66	Uysal, K. T. et al., Protection from obesity-induced insulin resistance in mice lacking TNF-alpha function. Nature, 389: 610-614, 1997.
C67	Wang, E. et al., Posttranscriptional regulation of protein expression in human epithelial carcinoma cells by adenine-uridine-rich elements in the 3'-untranslated region of tumor necrosis factor-alpha messenger RNA. Cancer Res, 57: 5426-5433, 1997.
C68	Wang, L. G. et al., Down-regulation of prostate-specific antigen expression by finasteride through inhibition of complex formation between androgen receptor and steroid receptor-binding consensus in the promoter of the PSA gene in LNCaP cells. Cancer Res, 57: 714-719, 1997.
C69	Watanabe, T. et al., Atherosclerosis and inflammation mononuclear cell recruitment and adhesion molecules with reference to the implication of ICAM-1/LFA-1 pathway in atherogenesis. Int J Cardiol, 66 Suppl 1: S45-53; discussion S55, 1998.
C70	Weisman, M. H., What are the risks of biologic therapy in rheumatoid arthritis? An update on safety. J Rheumatol Suppl, 65: 33-38, 2002.
C71	Whalen, J. D. et al., Adenoviral transfer of the viral IL-10 gene periarticularly to mouse paws suppresses development of collagen-induced arthritis in both injected and uninjected paws. J Immunol, 162: 3625-3632, 1999.
C72	Yoon, J. W. et al., Cellular and molecular mechanisms for the initiation and progression of beta cell destruction resulting from the collaboration between macrophages and T cells. Autoimmunity, 27: 109-122, 1998.
C73	Yoza, B. K. et al., Protein-tyrosine kinase activation is required for lipopolysaccharide induction of interleukin 1beta and NFkappaB activation, but not NFkappaB nuclear translocation. J Biol Chem, 271: 18306-18309, 1996.

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